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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/434,586	11/05/1999	JAMES H. WICKS	54905USA2A.002	4126
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32692 7590 08/26/2003

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EXAMINER

REDDING, DAVID A

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/434,586

Applicant(s)

WICKS ET AL.

Examiner

David A Redding

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8,9 and 11-42 is/are pending in the application.
- 4a) Of the above claim(s) 24-27 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8,10,14-17,21 and 22 is/are allowed.
- 6) ☒ Claim(s) 11-14,18-20 and 28-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 November 1999 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's arguments filed 9/9/02 have been fully considered but they are not persuasive.
2. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is improperly dependent upon claim 11. Claim 11 defines a markush group as comprising three components. Claim 12, dependent upon claim 11, broadens the same markush group to include twelve components. Claim 12 defines a broad limitation which is dependent upon a narrow limitation.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

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Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 11,12,18-20, are rejected under 35 U.S.C. 102(b) as being anticipated by USP 4,770,853 (Bernstein).

Bernstein discloses a device for performing a rapid immunodiagnostic test for group A streptococci using a phage associated lysin enzyme. Figures 1,5,6 illustrate the embodiment which reads on the claimed invention. Claim 12 specifies that the biological assay reagent can be antibodies or indicator chemistries. The lower portion (10) of the device comprise capture and control membranes (18,19) , the capture membranes being coated with **antigen** or antibody or other complementary ligands or receptors and can be used to determine the presence of different antigens or antibodies (col.5, lines 39-47). See the description of figures 1-6 and col.5, line 55 thru col.6, line 36.

5. Claims 11-13,18,19 are rejected under 35 U.S.C. 102(b) as being anticipated by USP 5,573,951 (Gombrich et al.).

Gombrich et al. disclose a multi-chambered blood culture assay device in which some of the chambers are separated by a seal which is breached by rotation. The device is disclosed as containing a nutrient growth media which reads on the claimed **nutrients**. Figures 4-8 illustrate the embodiment which includes the rotating seal (col.7, lines 27-52).

6. Claims 11-13,18-20,28-41 are rejected under 35 U.S.C. 102(e) as being anticipated by USP 6,189,688 B1 (Aneas).

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Figure 2 illustrates the embodiment which reads on the claimed invention. The device comprises at least three chambers. Chamber (9) contains a liquid (2), chamber 10 a powder (3), and the lower end (18) an empty third chamber. Separating chamber 9 and 10 is a rotating seal in the form of a disc (7). The reference suggests that the device can comprise papaverine sulfate and bicarbonate of soda, which are considered to constitute selective agents (col. 1, lines 19-67).

Allowable Subject Matter

7. Claims 8,9,14-17,21,22, are allowable over the prior art of record.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Conclusion

8. This application contains claims 23-27 drawn to an invention nonelected with traverse in Paper No. 6. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Redding whose telephone number is 703-308-3910. The examiner can normally be reached on M,T,Th,Fr, 7:30-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Warden can be reached on 703-308-2920. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



David A Redding
Primary Examiner
Art Unit 1744

D.A.R.